Meeting Summary
Organ Transplant Work Group
Fourth Meeting: July 14, 2015
MHCC, 4160 Patterson Avenue, Baltimore, MD 21215

Work Group Member Attending in Person:

Claudia Donovan, M.D.
Linda Ohler
Jessica Quintilian
Bill Rayfield, M.D.
Brigitte Sullivan
Anne Weiland

Work Group Members Participating by Phone:

Lori Brigham
David Leeser, M.D. (substitute for Sue Ostovitz)
Daniel Schwartz, M.D.
Nicole Stallings

Commission Staff Attendees:

Eileen Fleck, Chief, Acute Care Policy & Planning
Rebecca Goldman, Program Manager, Acute Care Policy & Planning
Kathy Ruben, Health Policy Analyst, Acute Care Policy & Planning
Paul Parker, Director, Health Care Facilities Planning & Development

Other Attendees:

Patricia Cameron, MedStar Health
Spencer Wildonger, Johns Hopkins Health System

Introductions

Ms. Rebecca Goldman opened the meeting at approximately 10:00 a.m. She introduced herself and asked group members present and participating by phone to introduce themselves. Following introductions, Ms. Goldman noted that this was the final meeting planned for the Organ Transplant Work Group.

Review of May Meeting Summary

Ms. Goldman stated that she had received feedback on the previous meeting minutes from Dr. Daniel Schwartz with CMS, who requested changes on page 7 to his comments

regarding CMS outcomes and requirements as well as the Medicare oversight certification process. Specifically, he asked that the meeting summary specify that the requirements refer to one-year graft survival and patient survival metrics as referenced in the CMS regulations. Ms. Goldman noted that the changes requested by Dr. Schwartz had been addressed in the updated meeting summary distributed to the work group. Ms. Goldman said that the meeting summary would be posted to the MHCC website following the meeting along with any additional work group member comments or feedback.

Discussion of Memorandum

Ms. Goldman asked for feedback on the memo from Anne Weiland and individuals from the Georgetown Transplant Institute that included their perspective on the presentation by Brigitte Sullivan and Dr. Massie from Johns Hopkins at the May work group meeting. Their presentation described an alternative approach to quantifying the demand for additional organ transplants. Ms. Goldman explained that the new draft State Health Plan (SHP) proposal backs away from the use of a need projection, but she still wanted to hear the perspective of other members.

Ms. Weiland asked whether MHCC would be removing the current policy regarding use of a utilization projection to determine when CON applications would be accepted. Ms. Goldman confirmed that is the direction proposed. She further stated that the alternative to demand forecasting being proposed is one in which the MHCC would open the door to applicants if the existing programs are operating at a prescribed threshold volume. While this could make it easier for entry into the process as an applicant, Ms. Goldman noted that the plan chapter would include review standards intended to assure that any new program proposed for addition in the state would meet a population need and provide improvements in the delivery of transplant services without resulting in an unacceptable level of negative impact on the existing system of care.

Dr. Claudia Donovan asked about the role of quality in determining whether a need exists for a new program. She noted that if centers are functioning at a high volume, then looking at the volume may not be as important as looking at quality. She stated that there are many intangibles in trying to get the quality standards on paper. Ms. Goldman noted that the draft standards do address quality issues. She opined, on the basis of existing program quality assessments, that problems in the quality of care were not likely to be triggers for accepting applications to establish new programs. Maryland is fortunate to have high quality programs. She explained that MHCC has proposed using other metrics to examine the need for additional program. She also noted that the burden of demonstrating need will be on the applicant rather than on MHCC. Ms. Weiland commented that her memo was in response to a particular methodology not about the use of other parameters.

Proposal for Need Threshold

Ms. Goldman explained that the new proposal does not include a demand forecast and qualifying threshold approach to need determination that creates opportunities for application filings, like the current plan. She suggested that perhaps MHCC would develop a bi-annual report that includes metrics that may be useful for evaluating whether a new program is needed, as noted on page 9 of the handout. Ms. Goldman suggested that the proposed bi-annual report could include the following information:

- *3 years of transplant center volume(Source: UNOS)*
- *3 years of utilization rates by organ type, living and deceased, and donor service area (Source: UNOS)*
- *3 years In-migration and out-migration volumes by DSA (Source: UNOS)*
- *The latest CMS quality reports (Source: SRTR)*
- *The Latest hospital quality reporting for hospitals with transplant centers (Source: MHCC)*
- *Latest organ donation rates, by organ type and DSA (Source: SRTR)*
- *CMS/UNOS policy updates (Source: CMS/UNOS)*
- *MHCC assessment of industry innovations and impact since last report*

When discussing the metrics, Ms. Goldman said that she was not sure how to project accurately organ donation rates using past utilization. Lori Brigham agreed that MHCC may not be able to project into the future, but at least it could determine the trend in organ donation rates. For example, she stated that if donation rates are flat then adding a transplant center is not going to increase organ donations. Ms. Goldman explained that the MHCC was not going to use trends in transplant rates as a specific criterion for evaluating the need for a project in the SHP because the burden of demonstrating the need for a new transplant program will be placed on the applicant.

Dr. Donovan asked for confirmation that the SHP chapter would be less rigid for applicants in terms of not looking strictly at numbers. Ms. Goldman agreed with Dr. Donovan. However, she noted that there are still volume thresholds that must be met in order for MHCC to accept applications and consider approval of a new program. Another work group member asked for confirmation that in addition to maintaining volume thresholds, quality measures would also be examined. Ms. Goldman agreed, and she added that the MHCC would look at quality to perhaps open the door to applicants and partly serve as a basis for justifying a new program.

Proposed Structural Changes to the State Health Plan Chapter

Ms. Goldman provided an overview of the proposed updates and revisions to the SHP chapter, which was last updated in 2002. Many of the revisions reflect changes that are consistent with other recently updated State Health Plan Chapters. She referred to the current and proposed table of contents for COMAR 10.24.15 on page 2 in the overview of updates and revisions. The proposed table of contents is significantly pared down from the current COMAR 10.24.15. Ms. Goldman noted that one of the biggest structural changes to the Chapter is that there will be no "Principles" section. This reflects the changes that have been made to other SHP Chapters that have been revised since 2002. She noted that the information contained in the current principles section is important, but will now be incorporated throughout the SHP instead of in a distinct section. She said that the goal of this change is to hold applicants more accountable to the principles in developing their applications.

The current SHP includes content in the issues and policies section that will now be included as Standards in the draft SHP Chapter. There will also be General Standards as well as Project Review Standards. Two of the three General Standards in the Acute Hospital Chapter are included in the current Organ Transplant Chapter of the SHP. The MHCC staff will be incorporating all three General Standards (by reference) in a draft revised Chapter. Ms. Goldman also noted that the additional proposed Project Review Standards were included on page 10 of the handout.

Ms. Goldman noted that one outstanding issue that had not yet been discussed by the work group is whether or not organ transplantation services must be limited to a teaching hospital or a hospital affiliated with a teaching hospital as is required in the current SHP. She noted that it is not a requirement for any other service regulated through the CON process nor is it a requirement of UNOS or CMS. Ms. Goldman asked for feedback on whether to maintain the standard.

Dr. Donovan commented that because transplantation is such a specialized service, as are some of the requirements, there are usually not transplantation programs at small stand-alone hospitals. Ms. Goldman agreed, but asked if there were any research studies or literature supporting the limitation of organ transplantation to teaching hospitals.

Dr. Leeser commented that transplant services should not be limited to teaching hospitals or a hospital affiliated with a teaching hospital because there are some very good transplantation programs in other hospitals. Ms. Weiland said that she is also not opposed to non-teaching hospitals performing transplants. However, she noted that volume requirements may be an issue at these hospitals. She noted that she would like to talk about the abstracts for studies regarding organ transplant volume that Ms. Goldman provided to work group members, when that issue is addressed during the meeting. Ms. Weiland further explained that if a

transplant center has adequate experience, then she does not think transplantation has to be done only in a teaching hospital. However, volume is a measure of experience.

Ms. Goldman noted that if the SHP mandates Certification by UNOS or CMS, than the metrics used by UNOS and CMS may take care of that issue. Dr. Donovan questioned where bone marrow transplants fit in these discussions. Ms. Goldman explained that the definition of organ transplant includes bone marrow and other cells, although the volume requirements may change. Dr. Donavan commented that much of the discussion seemed to center on solid organs, so she was not sure about whether bone marrow transplants were included. Ms. Goldman noted that FACT accreditation is a requirement. Ms. Fleck asked Dr. Donovan if she felt additional specific standards should be included in the Chapter for bone marrow transplants. Dr. Donovan responded that using the same standards as for solid organs should be sufficient.

Ms. Brigham asked about whether a CON is contingent on meeting the UNOS requirements or whether a hospital must first show that it meets the UNOS requirements before getting a CON. Ms. Goldman responded that the current SHP chapter requires a hospital to demonstrate that it can meet the UNOS criteria and the hospital's transplant program must be UNOS certified within the first year of operation.

Ms. Fleck asked if there were other comments related to the requirement that only teaching hospitals or hospitals closely affiliated with a teaching hospital provide transplantation services. Ms. Weiland asked for the definition of a teaching hospital, and Ms. Goldman read the definition shown below.

> *(7) Teaching hospital means a hospital that has more than 200 licensed beds; has a residency or fellowship training program fully accredited by the Accreditation Council for Graduate Medical Education (ACGME) with training programs appropriate to the type of transplant program offered; and has 24-hour on-site physician coverage by residents, fellows, or attendings.*

Ms. Goldman noted that three work group members voiced support for eliminating the requirement for affiliation with a teaching hospital, and she proposed deleting it. Ms. Ohler stated that she would prefer a teaching hospital provide transplantation services, but it should not necessarily be a requirement to establish a new center. Ms. Fleck asked whether the requirement was important with regard to training future doctors. Work group members commented that it was not a concern.

Ms. Goldman stated that the MHCC plans to delete the requirements for certification of physicians for transplantation in the new draft SHP because certification is covered under UNOS and CMS requirements. She requested feedback on this proposed change. Ms. Weiland

commented that the requirement should not be deleted in the new SHP Chapter. Dr. Donovan agreed. Although she agreed that it may be redundant, she questioned whether there is a good reason to take it out. Ms. Goldman asked if there should be any modifications to the requirement. Ms. Weiland suggested changing the requirement from "*certification"* to "*certification or licensure as appropriate*."

Ms. Goldman said that a related change to the SHP Chapter would be to include items related to support services found in other SHP Chapters. She read the proposed language to the committee members, as shown below, and on page 13 of the handout.

(b) Support Services

1. A transplant program shall provide information on Medicaid eligibility, supplemental coverage for prescription drugs, and vocational rehabilitation services for those patients without adequate insurance coverage.

2. An applicant should describe the level of support that it provides for vocational rehabilitation for patients with adequate insurance coverage.

3. A transplant program shall demonstrate that it has appropriate ancillary and support services, including pathology, laboratory, radiology, rehabilitation, social work, and mental health services.

Ms. Goldman asked for comments about adding new requirements about social services to which Dr. Schwartz replied that it would be like "reinventing the wheel" and very redundant. He noted that there is already a very robust organization in place to monitor transplant programs. Ms. Weiland agreed with Dr. Schwartz. Ms. Goldman stated that the overall consensus seemed to be to delete the language about support services but leave in the statement about certification requirements. She asked for any additional comments. There were none, so she moved on to standards found on page 11 of the handout.

Access Standard

Ms. Goldman noted that the draft access standard is a brand new standard and then read the draft standard to the work group. The draft standard is shown below.

Access

(a) Organ transplant services, of any type, should be accessible within three hours one-way driving time to at least 95 percent of Maryland residents.

(b) An applicant that seeks to justify the need for additional organ transplantation services on the basis of barriers to access shall:

1. Present evidence to demonstrate that barriers to access exist, based on studies or validated sources of information.

2. Present a credible plan to address those barriers. The credibility of the applicant's plan will be evaluated on whether research studies or empirical evidence from comparable projects support the proposed plan as a mechanism for addressing the barrier(s) identified, whether the plan is feasible, and whether members of the communities affected by the project support the plan.

(c) Closure of an existing service, in and of itself, is not sufficient to demonstrate an access issue or the need to establish a new or replacement organ transplantation service.

(d) Travel to a center located in a bordering region for an organ transplant is not considered an access issue if the drive time is less than three hours one-way.

Ms. Goldman stated that everyone seemed to be in agreement with the drive-time standard when the group previously discussed access. Ms. Brigitte Sullivan commented on the last proposed access standard suggesting that travel to a bordering region may indeed illustrate an access issue. The work group then discussed various reasons why an individual may go to another region to obtain a transplant including having family in another area or because of the reputation of a transplant team or specific doctor. Ms. Fleck explained that the idea of the standard was to make boundaries less restrictive with respect to evaluating the need for a transplant program. For example, for someone living close to the border of a health planning region, it may be just a 20 minute drive to another transplant center in another health planning region.

Ms. Goldman added that if someone drove from Baltimore to Washington, it would not be considered an access issue. However, she added that perhaps the language within the proposed SHP could be changed to show that travel in and of itself may not be an access issue. The group agreed that travel to a center located in a bordering region for an organ transplant in and of itself is not an access issue. Ms. Weiland mentioned that there a lot of reasons for traveling outside a region, such as the reputation of a center, family located out of state, or a physician's recommendation. Ms. Sullivan agreed with Ms. Weiland. However, Ms. Sullivan noted that access to organs differs among regions, so location matters. She commented that the organ procurement regions are not artificial boundaries, but rather do affect access to organs. Mr. Parker and Ms. Fleck emphasized that there needs to be justification beyond just travel time or traveling outside a region for a new program to be developed on the basis on insufficient access.

Need Standard

Ms. Goldman read the draft standard for need shown below.

Need

The need for a new organ transplantation center may be demonstrated based on the following criteria.

(a) Existing services in the applicable health planning region(s) have operated at the threshold volume for a period of three years.

(b) An applicant bears the burden of demonstrating how a proposed project will improve health care services, by:

1. Explicitly addressing existing underperformance or system deficiencies. Deficiencies may include, but are not limited to, a center closing or being decertified by CMS.

2. Explicitly addressing how the proposed project will increase the supply or use of donor organs for patients in Maryland. This may include, but is not limited to, technology innovations or living donation initiatives.

3. An applicant's need analysis for a proposed project shall account for the utilization trends for regions that include Maryland residents in the most recent published utilization report and any other regions from which it projects drawing patients.

(c) An applicant shall demonstrate that a proposed organ transplantation service can generate the minimum threshold case volume within the first two years of operation and will likely continue to sustain at least the minimum threshold case volume in subsequent years.

(d) An applicant that is part of a health system which operates an existing organ transplantation service in Maryland or a contiguous health planning region shall demonstrate how the proposal is cost effective and not duplicative of services.

(e) Closure of an existing service, in and of itself, is not sufficient to demonstrate the need for a new or replacement organ transplantation service.

Ms. Weiland asked why the wording in section (a) of the draft need standard demonstrates the need for an organ transplant program. Ms. Goldman explained that the wording in section (a) refers to a criterion for accepting applications for a new organ transplant program, not the approval of a new organ transplant program. Dr. Donovan requested

confirmation that pediatric programs do not have threshold standards in the draft Chapter, and Ms. Goldman confirmed that is the case. Ms. Weiland commented that the capacity of existing programs to absorb additional volume needs to be considered, especially because the thresholds are low.

Ms. Goldman returned to the concern raised by Ms. Weiland, and she further explained that while the volume thresholds open the door for new applicants, the threshold standards must be met over a period of three years which raises the standard for accepting applications.

Ms. Goldman clarified part (b) of the draft need standard by stating that the closing of a center is just a part of building a case for need. Work group members discussed this draft need standard in comparison to the current need standard, including the volume thresholds. It was confirmed by Ms. Goldman that the work group previously recommended that the threshold standards remain the same. It was suggested that the language in part (c) be changed to be consistent with the current Chapter in allowing a new program three years to meet the minimum threshold case volume rather than two years. The suggested revisions are indicated by the bold text in the draft standard shown below.

> *An applicant shall demonstrate that a proposed organ transplantation service can generate the minimum threshold case volume within **three** years of operation and will likely continue to sustain at least (**add the minimum threshold case volume for various organs**) in subsequent years.*

Ms. Weiland asked whether it was acceptable for a newly approved organ transplant program to remain at the threshold volume for several years. She commented that she would expect a program's volume to continue growing, if the program was needed, and the program was not just pulling volume away from other programs. Ms. Goldman responded that MHCC staff does not have a solid rationale for using other volume standards. She also explained that the volume standards are set to assure quality and cost efficiency. Ms. Weiland also recommended that the capacity of existing programs should be considered as part of the analysis of need. Ms. Goldman agreed with the idea of incorporating the capacity of existing programs into the analysis of an application. She asked for specific recommendations for addressing the issue. She noted that the volume of transplants for each program would be included in the proposed bi-annual report.

Ms. Goldman next referred work group members to a handout with the volume of transplants by program and organ type. She noted that one kidney transplant program saw an 80 case growth in volume in one year. Dr. Donovan pointed out that historically the program generally had a higher volume, so she would conclude approximately 50 additional cases were absorbed. Ms. Goldman explained that potentially the historic fluctuations in volume could be used to evaluate an existing program's ability to absorb an increase in volume. Ms. Fleck asked

the work group about having a standard specifically stating that an applicant must address the ability of existing transplant programs to handle an increase in transplants. A few of the work group members agreed with the suggestion.

Mr. Parker asked the work group how they would define capacity other than looking at the availability of organs and the number of transplant surgeons. Ms. Sullivan commented that there are other specialists involved, including staff who care for patients following a transplant. Ms. Weiland commented that programs are built around demand, and the current resources in use may not accurately reflect the ability of a program to accommodate additional transplant volume. Transplantation capacity is not easily defined; it is not as simple as adding positions or re-allocating beds. In addition, Ms. Weiland commented that probably none of the transplant programs are at maximum capacity due to the limited supply of organs. However, Dr. Donovan pointed out that programs may be able to increase organ procurement or to preserve and use organs more effectively through technological advances.

Ms. Sullivan asked how an applicant would evaluate the ability of other programs to handle additional organ transplants. Dr. Donovan commented that it is difficult to evaluate the ability of a program to handle additional organ transplants, and it may not be possible to provide definitive guidance to applicants. The burden of demonstrating the need for a new program will be on the applicant. Dr. Donovan mentioned that if the wait time for a screening appointment is six months, then that would be excessive. Ms. Fleck commented that it is helpful to have specific parameters, if they can be provided. Ms. Weiland commented that she disagreed with defining specific parameters and stated that the language previously suggested by Ms. Fleck seemed reasonable. Ms. Fleck asked if anyone else wanted to comment on the issue, and there were no additional comments.

Before beginning a discussion of the impact standard, Ms. Weiland asked a question about a CON requirement on page 13 of the work group handout, as shown below.

> *(a) An applicant for a solid organ transplant program shall demonstrate its ability to meet UNOS membership criteria and shall be UNOS certified within the first year of operation*.

Ms. Weiland was not sure if a program could operate before meeting the UNOS certification requirements. Mr. Parker said he viewed the standard as a performance requirement for a CON, i.e., if a new transplant program does not become UNOS certified in the first year of operation, then the CON would be voided. Ms. Weiland asked that the language be revised for clarity.

Impact Standard

Ms. Goldman then read the draft impact standard shown below.

Impact

(a) A new organ transplant service should not interfere with the ability of existing programs to maintain at least the annual threshold volumes defined in this chapter; and

(b) A project shall not have an unwarranted adverse impact on the cost of hospital services or the financial viability of existing Medicare-certified providers of organ transplantation services. A project shall also not have an unwarranted adverse impact on the availability of services, access to services, and quality of services. An applicant shall provide documentation and analysis that supports:

> *1. Its estimate of the impact of the proposed project on patient volume at other organ transplantation services in the same and contiguous regions. If volume is projected to shift from one or more existing organ transplantation centers as a result of the proposed project, the applicant shall quantify the shift in volume and the estimated financial impact on the organ transplantation center of any such service.*
>
> *2. Its estimate of any reduction in the availability or accessibility of a facility or service that will likely result from the project, including access for patients who are indigent or uninsured or who are eligible for charity care.*
>
> *3. Its estimate of any reduction in the quality of care at other providers in the same region or contiguous region that will likely be affected by the project.*

Ms. Weiland commented on section (a) stating that any new program would interfere with the annual threshold volume of an existing program because it would be taking organs from the existing program. Ms. Goldman said that a new applicant would have to address this issue. Ms. Fleck also commented that the impact on other programs would be evaluated based on factors other than volume shifts. Ms. Goldman discussed a specific hypothetical example and reviewed section (b) of the draft standard. Ms. Weiland commented that the language in section (b) addressed her initial concerns about the impact standard.

Ms. Goldman explained that the goal of the new draft standards is to give applicants enough direction to understand the Commission's expectations. She added that MHCC staff would appreciate input from the work group on how to clarify the draft standards. She further explained that the purpose of the biannual report with metrics is to identify those factors that will definitely be used to evaluate CON applications. She asked the work group if there were other issues that they would like to discuss.

Case Volume and Center Outcomes

Ms. Weiland wanted to discuss the stated preference for centers with higher volume compared to centers with lower volume. She noted that although lower volume programs can have good outcomes, most data suggest that high volume centers have better patient outcomes. She summarized her assessment of the abstracts that were shared by Dr. Klassen. Out of the eleven studies, she noted that six studies found that higher volume programs have better outcomes; two studies (one about liver transplants and one about kidney transplants) were equivocal regarding the relationship between volume and outcomes. Ms. Weiland also noted that one of the studies was about re-transplantation (not primary transplants), and one study did examine volume and outcomes. In her view, five studies were non-contributory in the argument about volume and outcomes. Ms. Weiland disagreed that the statement (policy 6) in the existing SHP chapter should be removed as was suggested by MHCC staff due to conflicting evidence because in her view there is evidence in the literature to suggest that higher volume programs do have better outcomes. Ms. Goldman commented that her understanding was that Dr. Klassen suggested that the literature on the relationship between volume and outcomes for transplant programs is mixed.

Ms. Goldman read the language of the existing policy, shown below, and asked for additional comments:

> *Policy 6: Fewer organ transplant services operating at higher volumes are preferable to more programs at threshold of minimum volumes.*

Dr. Donovan suggested prefacing the statement with "in general" because in general larger programs do have better outcomes because larger programs see cases that are more technically challenging and complicated. Ms. Fleck asked if anyone else wanted to comment on the issue. Dr. Bill Rayfield noted that even laypersons are starting to understand that higher volume programs have better outcomes. Ms. Fleck noted that there would be another opportunity to comment on draft regulations later. Another member suggested keeping the existing language in the SHP, and the work group overall seemed to favor maintaining the current policy.

Additional Revisions to Need Standard

Ms. Sullivan asked if additional language about quality could be added to the draft need standard on page 11 of the handout with draft standards. Specifically, she believes there should be an opportunity to consider applications for a new program, even if a program in the health planning region is below the threshold standard for a specific type of organ, when the program below the threshold standard is not meeting the CMS outcome standard for survival rates. Ms. Fleck commented that when the work group last discussed the issue, it was agreed

that it made sense to be cautious about using quality indicators because CMS seems to give programs a significant period of time to improve, and sometimes programs do improve significantly. Ms. Sullivan explained that she is concerned that there could be a gap of several years between a program having low volume and poor outcomes before the program closes, and a new program may be considered under the draft standard. Dr. Donovan agreed that Ms. Sullivan's proposed approach made sense. Ms. Sullivan also pointed out that an applicant would still have the burden of demonstrating that a new program is needed. Ms. Weiland agreed with Ms. Sullivan's proposed approach, but added that the outcome measures should be based on what is currently publically available.

Mr. Parker asked whether the CMS standard was quantifiable and could be added to the quality thresholds. Ms. Sullivan stated the CMS standards are quantified and publically available. Mr. Parker then explained that the text being discussed by the work group, which is currently included in a draft need standard, is more like a docketing rule and should be separately considered from the need standard. Dr. Donovan proposed that the docketing rule should refer to volume thresholds or the quality of the program as triggers for accepting CON applications for new transplant programs. It was mentioned that survival rates are calculated every six-months and if two of the reports are below CMS standards within four years, then the transplant program is considered problematic.

Ms. Goldman reminded the work group of remarks made by Dr. Schwartz at the previous meeting where he emphasized transplant programs have 210 days to improve and how rare it is for CMS to shut down a transplant program. It was also suggested that the docketing rule refer to all programs being above the threshold volume or a program is below the CMS outcome standards for patient survival and one-year graft survival.

Ms. Fleck stated that if work group members want to email specific suggestions, they would be welcome. She also noted that a draft document would eventually be posted for public comment and would present another opportunity to provide feedback to MHCC. Ms. Weiland asked about using other SHP chapters for guidance. Ms. Fleck explained how quality measures are incorporated into evaluating program quality for cardiac surgery programs, including recommendations for closure of a program, and the evaluation of a new cardiac surgery program.

Dr. Schwartz commented that when a program is flagged, it is based on a retrospective snapshot, and a program could already be on the way to improving. He also noted that SRTR reports and CMS outcomes are two separate metrics, and the SRTR reports use Bayesian analysis which is different than the approach used by CMS. A work group member asked Dr. Schwartz if he could comment on Howard University's transplant program that closed and the process leading to that decision. Dr. Schwartz was unable to comment on it. Ms. Fleck asked if

Dr. Schwartz could comment based on his general knowledge of programs that have shut down. He noted that among 160 programs that had been through the mitigation process, only 16 are no longer certified. Ms. Fleck asked if there were certain signs that a program is struggling and will likely shut down. She explained that such information could potentially be helpful in providing guidance to MHCC staff on how to evaluate a struggling program. Dr. Schwartz responded that he was unable to provide any suggested language.

Ms. Ohler noted that programs with low volume may begin to lose referrals, and it is more difficult to meet quality standards when volume is low. A single adverse event could make the difference between being in compliance and out of compliance with CMS standards. Dr. Schwartz commented that SRTR switched to using Bayesian analysis because it is helpful for keeping false positives to a minimum, which is important for accurately evaluating low volume program. Dr. Leeser noted that correlation coefficients are not that good for the models used by SRTR. Dr. Schwartz asked for confirmation that the data would be used to justify granting a CON for a new transplant program, and MHCC staff confirmed that is the case. Dr. Schwartz then commented that it is important to know how the data are put together by SRTR.

Ms. Goldman summed up the conversation by stating that there seemed to be agreement about using quality measures to consider when applications will be accepted, but the work group did not endorse a specific approach. She suggested that work group members send additional comments or proposals to MHCC staff by email. Ms. Fleck explained that the next step will be to post a draft for informal public comment. She noted that the draft would be posted on MHCC's web site, and MHCC staff would notify the work group members directly by email too. The meeting was adjourned at approximately 12:15 pm.